

REMARKS

With the entry of this amendment, claims 24, 25, 29, 31, 33, 34, 36, 37, 40-49, and 52 are pending.

Drawings

With the next communication from the Examiner, applicants respectfully request acknowledgment of the formal drawing filed on July 12, 2004.

Rejections Under 35 USC 112, second paragraph, indefiniteness

Applicants traverse the rejection to claim 33 because this is a proper dependent claim and is not “redundant.” Claim 24 recites a mean pore size of 13 to 17 nm, which can also be written as 15 ± 2 nm, and claim 33 further defines the invention to have a mean pore size of 15 nm. A mean pore size of 15 nm further defines a mean pore size of 13 to 17 nm. Because claim 33 further defines claim 24, claim 33 is in accordance with 37 CFR 1.75(c), which states that “[o]ne or more claims may be presented in dependent form, referring back to and further limiting another claim.”

Claim 39 has been canceled and has been represented as new claim 52, which follows the Examiner’s recommended language. The other claims have been amended in light of the Examiner’s recommended language in order to overcome the outstanding rejections.

Rejections Under 35 USC 112, first paragraph, enablement

Applicants traverse the rejection of claims 44 – 49 for lack of enablement. As discussed below, the Examiner’s rejection for lack of enablement is premised on claims 44 – 49 having “no working examples or data or evidence.” (See page 8, line 8 of the Office Action date July 15, 2004.) Applicants contend that there are working examples to support claims 44 – 49 and therefore the Examiner has not met his initial burden to provide a reasonable basis to question the enablement provided for the claimed invention. (See MPEP § 2164.04.)

Moreover, claims 44 – 48 are genus claims that are supported by representative examples. MPEP § 2164.01(c) states as follows:

For a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation. Proof of enablement will be required for other members of the

claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation.

Applicants will explain below how the claimed genera of claims 44 – 49 are sufficiently supported by the working examples of the specification.

Claims 44 and 45

Claims 44 and 45 respectively claim a starting factor VIII filtered with a specific activity of at least equal to 50 IU/mg or 100 IU/mg. The specific activity value of 0.47 IU/mg arrived at by the Examiner is not supported by the specification and the Examiner cites no literature reference of how this calculation was derived. The Examiner uses the following formula:

$$3 \times 113.5 \text{ liters}/835\text{g} = .47 \text{ IU/mg}$$

Applicants urge that specific activity is calculated as follows:

$$3\text{IU/ml} \times 1000 \text{ liters} \times 113.5 \text{ liters} = 340,500 \text{ IU}$$

$$340,500 \text{ IU}/835 \text{ g} = 407.78 \text{ specific activity}$$

A specific activity of 408 is within the recitations of claims 44 and 45. Therefore the claims are commensurate with the enablement provided by the disclosure. Accordingly, this rejection is improper and should be withdrawn.

Claims 46 and 47

Claims 46 and 47 respectively claim a starting factor VIII solution with a factor solution in a concentration of from approximately 2 to approximately 100 IU/ml and of from approximately 10 to approximately 50 IU/ml. Tables 1-3 respectively disclose a solution eluted from chromatography (a starting solution, i.e. the solution before filtering) of a factor solution in a concentration of 22 IU/ml, 15 IU/ml and 19 IU/ml which are within the recitations of claims 46 and 47. Therefore the claims are commensurate with the enablement provided by the disclosure. The Examiner's statement at page 8 of the Office Action dated July 15, 2004 that these claims are not supported by "working examples or data or evidence" is thus erroneous. Accordingly, this rejection is improper and should be withdrawn.

Claims 48 and 49

Claims 48 and 49 respectively claim a starting factor VIII solution with a protein content of approximately 0.05 to approximately 0.5 mg/ml and a protein content of approximately 0.1 to approximately 0.5 mg/ml. Tables 1-3 respectively disclose a solution

eluted from chromatography (a starting solution, i.e. the solution before filtering) of a protein content of 0.32 mg/ml, 0.09 mg/ml and 0.20 mg/ml which are within the recitations of claims 48 and 49. The Examiner's statement at page 8 of the Office Action dated July 15, 2004 that theses claims are not supported by "working examples or data or evidence" is thus erroneous. Therefore the claims are commensurate with the enablement provided by the disclosure. Accordingly, this rejection is improper and should be withdrawn.


Conclusion

It is respectfully submitted that this application is in condition for allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to telephone the undersigned at the number listed below if the Examiner believes such would be helpful in advancing the application to issue.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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Date


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